

AN ELECTRONIC BASED EXPERIMENTAL PROTOCOL HAS "ARRIVED"

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Background and Objectives

Historically Study Protocols are paper based, at the ICR each research group generated their own protocol template making documents difficult to follow for persons conducting out of hours support as well as the Home Office Inspector.

Other additional disadvantages experienced with the paper system such as potentially slow approval processes where study proposals are passed back and forth between submitter and approver, the lack of version control to approved documents or even the un-necessary flow of potentially "dirty" documents in to the animal

In attempt to revolutionise and harmonise our Study Protocol designs we have developed an online protocol and submission process. This has streamlined the process and eradicates many of "copy and paste" errors associated with previous versions.

 Items on this list require content approval. Your is, information on content approval. 	dension will not appear in public views until approved by someone with proper rights. More
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EXPERIMENTAL TITLE *	BOU TEST Physhacolarutic Study
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Creating a Document

Protocols are initiated via the internal intranet. It is possible for any member of staff to submit a protocol. Submitters are only permitted to view their own documents and each study must be assigned to one or more active PIL holders. This is made possible by the large volume of dropdown fields embedded within the document. To minimize data input errors Project and Personal Licences numbers along with PIL contact details have been uploaded to a separate database that links with the protocol and will fill in details automatically.



The submitter is encouraged to be as detailed as possible when explaining their proposal. The protocol should be detailed enough to permit repeatability of study conditions as well as ensuring other PIL holders involved with the study can follow

Particular attention is drawn to the objectives or hypotheses for the experiment to be clearly defined. A number of Pre-Populated drop down boxes are provided to ensure accuracy.

EXPERIMENTAL ANIMALS ARRIVE Guidelines		
ANIMAL ORIGIN	Charles River	
SPECIES	Ret	
STRAIN	CD	
SEX	O Malo	
	* Female	
AGE	© Both Sexes (6-8 Works (Fango/Alten)	
WEIGHT	225 - 250g (Range/Mean)	
TOTAL NUMBER	5	

ARRIVE Guidelines

The ARRIVE - Animal Research: Reporting of In Vivo Experiments guidelines are intended to improve the reporting of research using animals maximising information published and minimising unnecessary studies. The Electronic Protocol has been developed with full consideration to the ARRIVE guidelines, each title section has a direct link to the guidelines enabling the submitter to fully understand the requirements for each section. This places animal welfare at the core.

The protocol template has been designed to capture the spirit of the 3'rs through the questions it poses the submitter, aiding the publishing of work or repeating of experiments. The protocol is primarily a working document so a balance was found as to the areas of ARRIVE to include in the study design and areas to omit until the write up phase of the experiment.

SAMPLE SIZE CALCULATION ARRIVE Guidelines		
NO. OF EXPERIMENTAL ANIMALS	3	
NO. OF CONTROL ANIMALS	2	~
EXPERIMENTAL UNIT	Animal	¥



Electronic Submission and Version Control

Electronic submission and approval means that documents only require printing when approved, this eliminates the requirement to transfer paper items from outside of the facility reducing the risk of pathogen transferal and eradicates the risk of an unapproved version being used as the "official"

Version Control also means that changes are more easily tracked and that the approved version is easily identified.

EXPERIMENTAL PROCEDURES

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TUMOUR TYPE	BW 456
INDUCTION METHOD	Sub Cutaneous
INDUCTION SITE	Right Flank
TUMOUR SIZE LIMIT	12mm
MEASUREMENT REGIME	Twice Weekly
WEIGHING REGIME	Twice Weekly
CELL BATCH	12345
DATE SCREENED	
	27/09/2018
RESULT ATTACHED	* Yes
	○ No
SURGERY	□ Yes ☑ No
	No To be Determined
ANAESTHESIA/SURGERY/EUTHANASIA	
ANAESTHESIA	□ Yes
	≅ No
	☐ To be Determined
ANAESTHETIC METHOD and AGENT	N/A
ANALGESIA	* Yes
	○ No
ANALGESIC ADMINISTRATION ROUTE	Sub Cutaneous Injection
ANALGESIC REGIME	Vetergesic at 0 and 2/hvs
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Procedural Competency

Study Proposers are required to declare all regulated and Schedule 1 techniques to be performed within the study proposal in the procedural competency section of the submission. This will detail PIL holders whom are signed off within their Personal Training Record and those whom are working under supervision, In such cases a supervising PIL holder from the identified list must be indicated.

Competency Declarations are spot audited to Personal Training Records by the Named Training and Competency Officer and inaccuracies are treated as a non-compliance.

Joe Bloggs
4285 - Joe Bloggegher ac uk
Adverse Effects are not expected with this study,
Care should be taken when using warming equipment as not to overheat the immals.
Drug towardy in not expected as drugs have been closed before as a higher closego incide, occasionly among being reach to mires veryout close extends will be thousupply contracted throughout the study and will be under promptly if the exercise term (MHs) is breached, signified by evidence of sectory or on the advise of a Named Anneal Case and Whiteler Official (MPACMO) or Named Verentrally Suppose (MNR).
Advice will be promptly assight from the NACWO should any clinical signs develop, scored via bodyweight or constron and identification from the Grimace Scale.
- Abores effects from ord googs will include performant of the completion, with an ormal clase in to the large, see use a familiar heading continue which will exclude the large performant between the large three sections the region of the stamesh which lookal reduce the real of refuse. If resistance is excounted which we reclude got leave the most of refuse. If resistance is excountered which we reclude got leave the most got refuse the most performance of introduced to the trachine which the county region as in this case the leavening conflicts and the research and the served countries for a term described in the county region.
 All annuls will expensive more transiers effects from the procedures florre enricht will be subject to blood sampling from jugular or set veins or via connulies.
- Aseptic techniques will be used to minimae the risk of infection.
 Arenals will be immediately killed by a Schedule 1 method if any of the following clinical signs of 4 health occur. unable to membra on upright position or move, box of consciourness, loss of blood from any orlifou, greater than 20% body weight ioss suspend to 24 hours, denhose or lichergy involving failure to seately to hunger or thesis.
Contact Joe Bloggs and collect samples as detailed below.

Submission Process

editing and resubmission.

submitters and approvers will receive email notification of all status changes to the document. An approver will check the study proposal and either approve it or reject it, when approved the document will be printed, signed and dated. Rejected submissions will be electronically re-

At each stage of the submission process both

Approvers will be NACWO's or NACWO Trained.

directed to the submitter with an explanation for

The primary advantage of electronic approvals is the ease and speed of ensuring the document reaches the correct person, this allows the reviewer to check the study proposal at a time that they can give it full attention.

CHECK SAMPLES REQUIRED	
BLOOD	* Yes
	○ Ne
TISSUE	* Yes
	○ No
FIXED TUMOUR	○ Yes
	* No
FROZEN TUMOUR	○ Yes
	* No
OTHER	N/A (specify)
SAMPLE COLLECTION & PROCESSING DETAILS	Take a first superficial blood sample via the an diverting temporary cannula, and call the arrival by N covarious of anisatricos (through the cannula). Sample to be collected on the bepare and stored in an eppendiotiff, dearly blood the appreciatiff with MI, date of collection, the study number and entirel number.
PPL AUTHORITY DECLARATION *	YES - I have permission from the PPL Holder to Authority must be Sought and Granted by the Project License Holder to Perform Soudy under their Project License.
FORM STATUS •	* Draft
	○ Completed
	○ Re-aubmit
	Please mark. Completed when the form as needy to be submitted. The form will no submitted for opproved whom the form is seved as "Completed: By withman, the form you are confirming that you have read and checked that activities listed the study proposed are convered by the specific Protocol within the Propositions.
Attachments	Bodyweights - JB-18-7777 stox + Delete
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Features and Benefits

- Faster approval process
- · Drop-down boxes employed within the template to aid accuracy of information
- Author can save document as draft to re-edit prior to submitting
- Submitters must declare full Project License authority for their study
- Training and Competency auditing may commence prior to the study commencing.
- Version History allows both submitters and reviewers to track document changes and gives Quality Control as to the "Approved Version".